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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,367	08/14/2001	David Duffy	11641/36	6423

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WASHINGTON, DC 20005

EXAMINER
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WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 11/03/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n No.

09/928,367

Applicant(s)

DUFFY, DAVID

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-22,27,33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) 8-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-7,27,33 and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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#### **DETAILED ACTION**

Claims 1-3, 5-22, 27 and 33-34 are pending.

Claims 8-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5.

Claims 4, 23-26, 28-32 have been cancelled.

Claims 1-3, 5-7, 27 and newly added 33-34 are under examination.

#### ***Specification***

The objection to the specification with respect to the abstract is withdrawn in view of the amendments to the abstract.

#### ***Claim Rejections - 35 USC § 112, first paragraph***

Claims 1-3, 5-7, 27 and newly added 33-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record under paragraph A below.

***Response to Arguments***

Applicants argue that under the Guidelines for Examination of Patent Applications a strong presumption of an adequate written description of the claimed invention is present in the application when filed. Applicants further argue that the claims are directed to a method of detecting modification of a target molecule of a biochemical pathway and not to the biomolecules themselves. The first group of biomolecules that are immobilized on the substrate can be any biomolecules so long as at least one of the biomolecules is a target member of a biochemical pathway, as recited in the claims. Applicants further urge that several examples of the types of pathways, biomolecules and medications are listed in the specification.

In reply, simply enumerating the different types of biomolecules and the other undefined parameters in the claims is not necessarily complying with the written description. As applicants stated, there are numerous and different members of a biochemical pathway, let alone, a first and second members of these pathways. This different biochemical pathway is but only one of the numerous undefined variables of the claimed invention. For example, the claim recites for the modifications that can be imparted to a target biomolecules having undefined structures. One skilled in the art is therefore left to

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determine which different combinations of the undefined claimed parameters can be combined to achieve applicants' objective of identifying a modified biomolecules. The specification fails to describe which biomolecules from the list can be made either singly or in combination with one another to form an array. A single array can include millions of the same or different biomolecules. The specification does not describe which of these different biomolecules have been made into a single array. More importantly, how such array can prevent interaction of the molecules therein such that binding is only to the target. This problem is made more complex for an array in solution. It does not describe the step by which the different components are separated or identified when in solution. It does not provide molecular level information on how proteins interact to control cell behavior and physiology. This is especially so in view of the boundless network of a biochemical pathway. It is a sequential collection of processes or reactions a cell uses to transmit stimuli. Each of processes or reactions usually involves a series of interactions between two or more biomolecules. One biomolecule may modify the other such that the modified biomolecule is activated or inactivated. Thus, mere listing the components of an array does not equate to a specific description of the biomolecules collectively. The specific

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description in the specification relates to kinase and its pathway as rAfk. In the analysis of biomolecule pathway, where every inconceivable reaction occur along the way, one skilled in the art would not have deemed the specific description sufficient. The specific written description is so specific that would lead one skilled in the art only to that specific pathway for a biomolecule.

B. The as-filed specification fails to provide a description of a method as recited in claim 1, claim 33 and claim 34. Applicants point out support for the newly amended claims at paragraph 21, pages 8-9 of the instant specification.

A review of the cited section does not reveal support for e.g., step a) of claim 1. This section merely refers to the copending application, which recites broadly a polymer gel mask. The copending application has not been incorporated as essential material to the present application. Accordingly, the steps of claim 1 or newly added claims 33 and 34 are not supported in the as-filed specification.

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 23-29 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

***Response to Arguments***

In view of the amendments to the claims, the rejection of the claims under this statute no longer applies.

However, newly amended claims 1-3, 5-7, 27 and 33-34 are rejected as follows:

1. Claim 1 is indefinite as to the method by which a polymer gel mask is placed such that it defines openings that can contact with a substrate, especially in the absence of positive support in the specification. It is not clear as to the difference between a first group of biomolecules from a second group since the specification does not recite for said first and second groups of biomolecules. Furthermore, it is not clear as to the method by which a target member of a biochemical pathway is detected, absent positive support in the specification. There seems to be a lack of nexus among the process steps. For example, it is not clear as to the relevance of step a) to the method of detecting modification of a target member of a

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biochemical pathway, especially in the absence of positive support in the specification.

2. Claims 2 and 3 are unclear as to the different types of biomolecules for the first and second group of biomolecules in the absence positive support in the specification.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).



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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-7, 27 and newly added 33-34 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Borrebaeck et al (2001/0053520) for reasons advanced in the last Office action.

***Response to Arguments***

Applicants urge that Borrebaeck et al is not prior art since it was filed on 3/16/01. The instant application, is argued, to claim priority from U.S. provisional Application No. 60/225,363.

In response, Borrebaeck claims priority to provisional application No. 60/192,256 filed on Mar. 27, 2000. This is earlier than the instant provisional application filing date of March 16, 2001. Therefore, Borrebaeck is a proper prior art as it antedates the instant priority date.

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Claims 1-3, 5-7, 27 and newly added 33-34 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Felder et al (6,232,066 equivalent to WO 9932663) for reasons set forth in the last Office action.

In view of the amendments to the claims, Felder no longer applies, as argued by applicants.

No claims are allowed.

#### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated

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from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims 8-22 drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

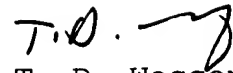
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

tdw

October 30, 2003